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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

5640 Anita 5/15/01

Applicant's or agent's file reference L0461/7034WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/10424	International filing date *(day/month/year)* 13 MAY 1999	Priority date *(day/month/year)* 13 MAY 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant LUDWIG INSTITUTE FOR CANCER RESEARCH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
01 NOVEMBER 1999	23 OCTOBER 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Jennifer Nichols (Huey) by my mean Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet) (July 1998)★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US99/10424

I. Basis of the report

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed

[X] the description:
pages 1-47, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

[X] the claims:
pages 48-56, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

[X] the drawings:
pages 1-8, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

[X] the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of ____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language ____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 15-24, 29-55, 60-65

because:

☐ the said international application, or the said claim Nos. _ relate to the following subject matter which does not require international preliminary examination *(specify)*.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _ are so unclear that no meaningful opinion could be formed *(specify)*.

☐ the claims, or said claims Nos. _ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 15-24, 29-55, 60-65 .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1-7, 12-14, 25-28, 56-59	YES
	Claims	8-11	NO
Inventive Step (IS)	Claims	1-7, 25-28, 56-59	YES
	Claims	8-14	NO
Industrial Applicability (IA)	Claims	1-14, 25-28, 56-59	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 8-11 lack novelty under PCT Article 33(2) as being anticipated by Hillier et al.

Hillier et al teach a fragment of isolated nucleic acid molecule of SEQ ID NO:1 or SEQ ID NO:4.

Claims 12-14 lack an inventive step under PCT Article 33(3) as being obvious over Hillier et al.

Hillier et al teach as set forth above. However, the reference fails to teach a vector and a host cell.

It would have be obvious to use the nucleotide taught by Hillier et al to make a fragment. One of ordinary skill in the art would have been motivated to make a vector and subsequently transfect the fragment into a host for the purpose expressing protein or replicating the nucleotide, or storage.

Claims 1-7, 25-28 and 56-59 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a SEQ ID NO: 1 or SEQ ID NO:4, and a composition therefore, or a kit.

Claims 1-14, 25-28 and 56-59 meet the criteria set out in PCT Article 33(4), for industrial applicability.

Applicant argues that Hillier does not apply as art because Claim 8 recites that the nucleic acid molecules exclude nucleic acid molecules which consist only of SEQ ID NO: 10 or 11. Hillier et al. teaches a nucleic acid molecule consisting of a fragment of SEQ ID NO: 11, and therefor does not meet this negative limitation. Therefor claims 8-11 lack novelty, and claims 12-14 lack inventive step.

---------- NEW CITATIONS ----------
NONE

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): C07H 21/02; C12Q 1/68; C12P 21/04; C12N 1/20, 15/00 and US Cl.: 435/6, 69.1, 252.2, 320.1; 536/23.1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/10424

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :C07H 21/02; C12Q 1/68; C12P 21/04; C12N 1/20, 15/00
US CL : 435/6, 69.1, 252.2, 320.1; 536/23.1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/6, 69.1, 320.1; 536/23.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

MEDLINE, APS, STN

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X - Y	Database GENBANK-EST, Accession Number AA004587, HILLIER et al . Generation and Analysis of 280,000 Human Expressed Sequence Tags. 07 May, 1997	8-11 ------ 12-14
X,P --- Y,P	Database GENBANK, Accession Number AA863443, NCI-CGAP, National Cancer Institute, Cancer Genome Anatomy Project (CGAP), Tumor Gene Index. . 13 May 1998.	8-11 ---------- 12-14, 25, 26

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 25 AUGUST 1999	Date of mailing of the international search report 20 OCT 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LIN SUN-HOFFMAN Telephone No. (703) 308-0196

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
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BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claim(s)1-14, 25-28, 56-59, drawn to an isolated nucleic acid molecule.
Group II, claim(s) 15-24, drawn to an isolated polypeptide.
Group III, claim(s) 29-34, drawn to a method of diagnosing a disorder with expression of a RUR-1.
Group IV, claim(s)35-43, drawn to a method of treating a subjecting with a disorder with expression of a RUR-1.
Group V, claim(s) 44-46, drawn to a method for enriching selectively a population of T cells with cytotoxic T cells specific for a RUR-1.
Group VI, claim(s) 47-55, drawn to a vaccine composition of RUR-1.
Group VII, claims 60-65, drawn to a method for determining the prognosis fo a disorder characterized by expression of a RUR-1.

The inventions listed as Groups I-VII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions I, II and VI are unrelated because the polynucleotides of invention I can be used in hybridizations assays whereas the inventions of II and VI cannot, the proteins of invention II can be used in affinity purification schemes and to make antibodies, whereas the polynucleotides of invention I cannot, the vaccine of invention VI can be used in pharmacutical treatment whereas the inventions of I and II cannot. The methods of inventions III, IV, V and VIII are distinct because they either treat different diseases as are completely unrelated to treatment (ie hybridization assay).

The inventions of Groups II, IV, V and VII are materially distinct methods which differat least in objectives, method steps, reagents and/or dosages and/or schedules used,
response variables, and criteria for success.

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :
C07H 21/02, C12Q 1/68, C12P 21/04, C12N 1/20, 15/00

A1

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(71) Applicant *(for all designated States except US)*: LUDWIG INSTITUTE FOR CANCER RESEARCH [CH/US]; 605 Third Avenue, New York, NY 10158 (US).

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(81) Designated States: AU, CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: TUMOR ASSOCIATED ANTIGEN ENCODED BY THE REVERSE STRAND OF A NEW UBIQUITOUSLY EXPRESSED GENE

(57) Abstract

Nucleic acid molecules derived from the antisense strand of a novel ubiquitously expressed gene, RUR–1, are provided. The RUR–1 antisense nucleic acids code for polypeptides which are expressed preferentially in tumor samples and tumor–derived cell lines. Nucleic acids comprising the ubiquitously expressed gene and fragments thereof also are provided. Also provided are polypeptides encoded by those nucleic acids, functional homologs, modifications and variants of the foregoing, useful fragments of the foregoing, as well as therapeutics and diagnostics related thereto.

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